ST. JUDE MEDICAL

510(K) SUMMARY

K070166

APR - 6 2007

1. ADMINISTRATIVE INFORMATION

Name:	St. Jude Medical
Address:	6550 Wedgwood Road North, Suite 150
	Maple Grove, MN 55311
Phone:	763-463-5713
Fax:	763-488-9780
Contact Person:	Jeff Sturm
	Senior Regulatory Affairs Specialist
Date:	January 17, 2007

2. DEVICE INFORMATION

Name of Device:	Strada™ Carotid Guiding Sheath
Common Name:	Access Sheath, Introducer
Classification Name:	Catheter Introducer
Product Code:	DYB

3. PREDICATE DEVICE INFORMATION

The predicate device is the Destination® Carotid Guiding Sheath manufactured by Terumo and cleared by premarket notification in 2005 (K052185).

4. DEVICE DESCRIPTION

The Strada™ Carotid Guiding Sheath is designed to perform as an introducer and a guiding sheath. The device is a single-use system that consists of a delivery sheath with hemostatic valve and dilator. Upon removal of the dilator, the delivery sheath provides a pathway for diagnostic and interventional devices into the vasculature.

The Strada™ Carotid Guiding Sheath is available in 80 and 90cm lengths. The sheath has an 8F outer diameter and 6F inner diameter. The distal end is straight, has a hydrophilic coating (20cm) and has a radiopaque marker approximately 2.5 mm from the tip. The device is provided sterile and non-pyrogenic.

5. INTENDED USE

The Strada™ Carotid Guiding Sheath is indicated for the introduction of diagnostic and therapeutic devices into the human vasculature including, but not limited to, the carotid artery.

The intended use is identical to the predicate device.

6. TECHNOLOGICAL CHARACTERISTICS

The device design and material types are key features that determine performance of the device. The components and material characteristics of the device are substantially equivalent to the predicate device. Both devices are used manually by the user.

7. SUMMARY OF NON-CLINICAL TESTING

Non-clinical testing of the Strada™ Carotid Guiding Sheath includes in vitro bench testing, animal evaluation, biocompatibility testing, shelf-life and package testing and sterilization validation. Results of the testing demonstrate that the Strada™ Sheath design meets product specifications and intended uses.

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Strada™ Carotid Guiding Sheath in this 510(k) is substantially equivalent to the Terumo Destination® Carotid Guiding Sheath (K052185). The intended use, design, material types, technology, and performance of the Strada™ Sheath is identical to the predicate device. There are no differences between devices which would raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

St. Jude Medical
c/o Mr. Jeff Sturm
Senior Regulatory Affairs Specialist
6550 Wedgwood Road North, Suite 150
Maple Grove, MN 55311

APR - 6 2007

Re: K070166
Strada™ Carotid Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 30, 2007
Received: April 2, 2007

Dear Mr. Sturm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Strada™ Carotid Guiding Sheath

Indications for Use:

The Strada™ Carotid Guiding Sheath is indicated for the introduction of diagnostic and therapeutic devices into the human vasculature including, but not limited to the carotid artery.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070166